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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,816	08/27/2001	Jacobus M. Lemmens	ADP-016US2	1906

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/938,816	Applicant(s) LEMMENS ET AL.
	Examiner Sharmila S. Gollamudi	Art Unit 1616

-- Th MAILING DATE of this communication appears on the cover she t with th correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-27 are included in the prosecution of this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 11, 14-18, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davison et al (4879303).

Davison et al teach the pharmaceutically acceptable salts of amlodipine such as amlodipine maleate in a pharmaceutical composition for treating angina and hypertension. The reference discloses the preferred pH of the composition to be close to that of the blood pH of 7.4 because it can be readily biocompatible (col. 2, lines 22-31). The pH of amlodipine maleate is taught to be 4.8 (Table 1). The active in formed into a tablet or capsule containing microcrystalline cellulose and dibasic calcium phosphate (col.2, lines 50-60). Davison et al teach the use of sodium starch glycollate in

the pharmaceutical composition (Table 3). Davison et al teach the method of compressing the composition into a tablet form and the method of filling the capsules.

Davison et al do not teach the instant pH of the composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the pH of the composition with known pH adjusting agents such as sodium glycollate as taught by Davison et al to have a pH closer to that of the blood to improve biocompatibility. Further, Davison discloses the pH of the instant (4.8) and the use of dibasic calcium phosphate in the composition; therefore a skilled artisan would recognize that this combination would yield a pH within the recited range.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davison et al (4879303) in view of EP 0089167.

As set forth above, Davison et al teach a pharmaceutical composition containing amlodipine maleate.

Davison et al do not teach the amount of amlodipine maleate.

EP teaches a pharmaceutical composition containing amlodipine and preferable its salt form, amlodipine maleate. Tablets and capsules contain 1 to 10mg preferably to treat cardiac condition (pg. 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the instant recited range of active since EP teaches this amount to effectively treat cardiac conditions.

Claims 10 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davison et al (4879303) in view of Sherwood et al (5585115).

As set forth above, Davison et al teach a pharmaceutical composition containing amlodipine maleate.

Davison et al do not teach a coated tablet or specify the type of granulation (wet/dry).

Sherwood et al teach a method of improving compressibility in tablets using microcrystalline cellulose. Sherwood discloses the three general methods of preparing solid dosage forms: dry granulation, direct compression, and wet granulation (col. 1, lines 64-67). Sherwood discloses that the method depends on the drug and excipients. Lastly Sherwood teaches the optional use of a hydrophobic coating to provide a sustained release (col. 12, lines 60-66).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Davison et al and Sherwood et al since Sherwood teaches the art of tabletting and using a g method depending on the drug and excipients. Further, Sherwood teaches the use of tablet coatings to provide for sustained release.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davison et al (4879303) in view of Sherwood et al (5585115) in further view Schobel (4687662).

As set forth above, Davison et al teach a pharmaceutical composition containing amlodipine maleate. Sherwood et al teach the method of making a solid dosage form.

The references do not specify the particle size of the active.

Schobel discloses a therapeutic effervescent composition. Schobel teaches the generally the preferred particle size when tabletting a solid dosage form. The reference discloses a particle size less than 100 microns has processing problems such as poor mixing and compressibility. (Col. 4, lines 31-45)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use particle sizes above 100 microns for a solid dosage form since Schobel teaches fine particles less than 100 microns tend to cause processing problems such as poor mixing and compressibility. One of ordinary skill in the art would expect similar results since Schobel teaches the particle size for making a solid dosage form.

Claims 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davison et al (4879303) in view Schobel (4687662).

As set forth above, Davison et al teach a pharmaceutical composition containing amlodipine maleate.

Davison et al do not specify the particle size.

Schobel discloses a therapeutic effervescent composition. Schobel teaches the generally the preferred particle size when tabletting a solid dosage form. The reference discloses a particle size less than 100 microns has processing problems such as poor mixing and compressibility. (Col. 4, lines 31-45)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use particle sizes above 100 microns for a solid dosage form since Schobel teaches fine particles less than 100 microns tend to cause processing

problems such as poor mixing and compressibility. One of ordinary skill in the art would expect similar results since Schobel teaches the particle size for making a solid dosage form.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG

October 31, 2002

MICHAEL G. HARTLEY
PRIMARY EXAMINER